Ethics in Medical Research: A Handbook of Good Practice

Trevor Smith, Cambridge, UK, Cambridge University Press, 1999, 403 + xvii pages, £29.95/US$47.95.

Research ethics is a very exciting field at the moment. Important public debate is continuing at national and international levels, concerning the proposed revisions to the Declaration of Helsinki and the Council for the International Organisation of Medical Sciences (CIOMS) guidelines, the proposed European clinical trials directive and the recent Good Clinical Practice guidelines. There is also debate about obtaining, using and storing genetic, and tissue, samples.

This ferment has resulted in a wealth of guidelines and learned articles, but as yet there are few useful and up-to-date book-length discussions of the field. This is partly due to the increasing diversity of types of research (including research design), and the variety of the contexts of research (the hospital-based clinical trial is arguably no longer typical of medical research). However, it is also to do with what such a book is supposed to do. Recent works like Baruch Brody's *Ethics of Biomedical Research* (OUP, 1998) give, in effect, an analytical commentary on the international guidelines; the classic work by Robert Levine (*Ethics and Regulation of Clinical Research*, Yale University Press, 1988) gives a philosophical justification for the consensus position that grew up around research ethics in the 1980s, following the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research's report, (the *Belmont Report*, 1978), and Don Evans and Martyn Evans seek to link the theory of research ethics to the practice of research ethics review in their *A Decent Proposal* (John Wiley and Sons, 1996).

The new (or even established) researcher or member of a research ethics committee, as distinct from the research ethics specialist, is thus faced with a rather unhelpful literature. A handbook is needed to give them a briefing on the main issues that concern them, to suggest approaches to these issues, and to lay out a framework for analysing research protocols in order to make reasonable and responsible decisions about them. Trevor Smith's book seeks to be that handbook.

This book covers an impressive range of topics, from epidemiology to xenotransplantation. It is clearly written. Perhaps reading it from cover to cover is not to be advised, as there is no "narrative" (handbooks normally don't aim at plot!), but as a work to be dipped into it fits the bill. In general, its treatment of the topics it covers is fair and reliable, and for this alone it can be recommended to research ethics committee members.

None the less, this work has its weaknesses. There are good chapters on audit and post-approval monitoring, but these reflect only one solution to these problems, and need more context and discussion. Analytically, this is a work of no great depth, since it concentrates on the pragmatics of review—what questions to ask, and what sorts of answer to look for. This is probably acceptable for clinical trials, in that we are now relatively sophisticated and stable in our collective understanding of this kind of research, at least where the research takes place in the UK. In some of the other areas covered, this degree of simplicity may be misleading. The chapter on xenotransplantation, for instance, is so brief that it cannot reasonably cover the topic or the issues around it in a way that does justice to this highly controversial issue. If a topic like xenotransplantation or gene therapy is to be covered, there is a good case for giving more analytic examination of the issues, in order to account for the lack of consensus, and perhaps to assist the development of one.

There is a general difficulty throughout the book, which Dr Smith makes a number of attempts to resolve. How far should "research ethics review" be attempting to give substantive "ethical" judgments (for example, is embryo research moral or immoral in itself, notwithstanding the consent and licensing arrangements?) This next problem bedevils the research review process itself (it is no failure of Dr Smith's): is a research ethics committee a bioethics committee, a regulatory committee, a peer review, or something else again? Or, to put it another way, can a research ethics committee restrict itself to consideration of the ethics of process, or must it consider also substantive ethics? It is no criticism of Dr Smith that he does not resolve this problem; his book only makes clear how pressing this difficulty actually is.

Some features of this book will make it vulnerable to change (in particular the chapters on fast-changing areas of medicine, such as genetics, and of the law, such as data protection and personal medical information). None the less, this book will be a useful tool for members of research ethics committees, and researchers planning their projects. Dr Smith is to be congratulated on reducing so much to manageable proportions.

RICHARD E ASHCROFT
Department of Primary Health Care and General Practice, Imperial College, London

Organ Transplants from Executed Prisoners

Louis J Palmer Jr, Jefferson, North Carolina, US and London, McFarland and Company, 1999, 156 pages, £26.25/$35.

In *Organ Transplants from Executed Prisoners*, Louis Palmer proposes alleviating the urgent shortage of organs for transplantation by requiring condemned felons to donate their vital organs after execution. The book proceeds as follows.

In his first chapter Palmer reviews the development of the quasi-property rights relating to the bodies of the dead, including the right to dispose of one's own body by means of a will and the right of relatives to bury it. In the second chapter, The Market for Human Body Parts, he goes on to review the current American laws restricting the sale of body parts in order to show that death-sentence removal might be permissible within established principles of law. A C MacDonald has recently provided a good review of the legal restrictions placed upon access to organs of the deceased[1] in which he points out that despite the fact that a large pool of potential donors exists, legislators and the public have consistently and severely restricted access to them—with good justification.

In a most remarkable sequence in the same chapter, Palmer goes on to note that in China, where organs are taken from executed prisoners: "The frequency and volume of executions are traced directly to an international black market in human body parts". This is a telling argument against such practices. Nevertheless, Palmer continues to argue for required organ